United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 9, 2002 Decided June 14, 2002

No. 01-5278

National Mining Association, et al., Appellants

v.

Department of Labor, et al., Appellees

Appeal from the United States District Court for the District of Columbia (No. 00cv03086)

Mark E. Solomons argued the cause for appellants. With him on the briefs was Laura Metcoff Klaus.

Sushma Soni, Attorney, United States Department of Justice, argued the cause for federal appellees. With her on the brief were Roscoe C. Howard, Jr., United States Attorney, and Mark B. Stern, Attorney, United States Department of Justice.

Thomas E. Johnson argued the cause for appellees United Mine Workers of America. With him on the brief were Grant Crandall and Judith Rivlin.

Before: Edwards and Tatel, Circuit Judges, and Silberman, Senior Circuit Judge.

Opinion for the Court filed Per Curiam.

Per Curiam: This lawsuit challenges regulations issued by the Secretary of Labor pursuant to the Black Lung Benefits Act, as amended, 30 U.S.C. ss 901-945 (1994) ("BLBA" or "Act"). The District Court upheld the regulations against all challenges. This appeal followed. For the reasons stated herein, we affirm in part and reverse in part. The case will be remanded to the District Court with instructions to remand the case to the Department of Labor for further proceedings consistent with this opinion.

I. Background

The BLBA is a federally administered law providing benefits to coal miners who are totally disabled due to pneumoconiosis, also known as black lung disease, and to the surviving dependents of miners who died of the disease. Under the Act, coal mine operators are responsible for paying benefits to miners whose death or total disability due to black lung disease arose out of employment in the mines. 30 U.S.C. s 932. Black lung disease encompasses a cruel set of conditions that afflict a significant percentage of the nation's coal miners with "severe, and frequently crippling, chronic respiratory impairment." Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 6 (1976) (citing, inter alia, S. Rep. No. 91-411, at 6 (1969)). It is caused by the "long-term inhalation of coal dust." Id. A rare and serious form of the disease, known as "complicated pneumoconiosis," results in pulmonary impairment and respiratory disability. Id. at 7. It can lead to cardiac failure and can contribute to other causes of death. Id. The purpose of the BLBA "is to satisfy a specific need created by the dangerous conditions under which [coal miners have] labored--to allocate to the mine operator[s] an actual, measurable cost of [their] business." Id. at 19.

A miner or his survivor may seek benefits under the Act by filing a claim with the District Director in the Department of Labor's Office of Workers' Compensation Programs ("OWCP"). After investigating the claim, the District Director determines whether the claimant is eligible for benefits and which employer will be held responsible. See 20 C.F.R. ss 725.301-725.423 (2001) (all citations to the Code of Federal Regulations will be to the 2001 edition unless otherwise noted). If the employer cannot be identified, the claim is paid out of the Black Lung Disability Trust Fund ("the Fund"), which is financed by a tax on coal. See 30 U.S.C. ss 932, 934; 26 U.S.C. ss 4121, 9501(d)(1). Either party may appeal the District Director's determination and request a hearing before an Administrative Law Judge ("ALJ"). 20 C.F.R. ss 725.450-725.480. The ALJ's decision may be appealed to the Department of Labor's Benefits Review Board, id. s 725.481, and then to the Court of Appeals for the circuit in which the impairment occurred, 33 U.S.C. s 921(c); 20 C.F.R. s 725.482.

In 1997, the Secretary of Labor ("the Secretary," "the Department," or "the government") issued a notice of proposed revisions to the rules governing the adjudication of miners' claims under the BLBA. See Regulations Implementing the Federal Coal Mine Health and Safety Act of 1969, as Amended, 62 Fed. Reg. 3338-435 (proposed Jan. 22, 1997). The Secretary received approximately 200 comments and held two public hearings on the proposed rules. The Secretary also consulted the National Institute for Occupational Safety and Health ("NIOSH"), the federal agency charged with researching occupational health. See 29 U.S.C. s 671. Congress directed the Secretary to consult with NIOSH to establish criteria for medical tests to determine whether coal miners are totally disabled. 30 U.S.C. s 902(f).

In 1999, the Secretary issued another notice, announcing revisions to certain proposed regulations. See Regulations Implementing the Federal Coal Mine Health and Safety Act of 1969, as Amended, 64 Fed. Reg. 54,966-55,072 (proposed Oct. 8, 1999). After receiving more comments and testimony and consulting NIOSH and other experts, the Secretary

promulgated the final rule, which would go into effect on January 19, 2001. See Regulations Implementing the Federal Coal Mine Health and Safety Act of 1969, as Amended, 65 Fed. Reg. 79,920-80,107 (Dec. 20, 2000).

The appellants in this case include mine operators, insurance companies, and the National Mining Association (collectively "NMA"). The BLBA requires coal mine operators to purchase insurance to cover their liabilities under the Act. See 30 U.S.C. s 933 (governing employers' insurance arrangements); 20 C.F.R. Part 726 (entitled "Black Lung Benefits; Requirements for Coal Mine Operator's Insurance"). The Secretary of Labor anticipates that the new rules will impose costs on mine operators in the form of higher insurance premiums. See 65 Fed. Reg. at 80,030. The Secretary's initial analysis indicated that, in the long term, the new rules would cause operators' insurance premiums to go up by about 39.3%, resulting in total annual costs to the industry of approximately \$57.56 million. Id. The Secretary's analysis also suggested that the overall approval rate for claims against responsible coal mine operators would increase from 7.33% to no more than 12.18%. Id. at 80,036. It is not clear how much of this anticipated increase is attributable to an anticipated increase in approval of claims that are already pending, and how much is attributable to claims that have not yet been filed.

Almost immediately after the final regulations were announced, appellants sought declaratory and injunctive relief in the United States District Court for the District of Columbia. See Am. Compl. p 1, reprinted in Joint Appendix ("J.A.") 1. They challenged many of the rules as impermissibly retroactive. See id. pp 19-23. They alleged that many of the rules violated the BLBA or applicable provisions of the Longshore and Harbor Workers Compensation Act ("LHWCA" or "Longshore Act"), 33 U.S.C. ss 901-950, many provisions of which are incorporated by reference into the BLBA by 30 U.S.C. s 932(a). See Am. Compl. pp 24-26. They alleged that some of the rules impermissibly shifted the burden of proof. See id .pp 27-32. They alleged that certain rules ran afoul of the right to a full and fair hearing, treated

parties unequally, or were arbitrary, capricious, and an abuse of discretion in contravention of the Administrative Procedure Act ("APA"). See id. pp 33-43. Finally, they alleged that the rulemaking procedure was inadequate and that the rules violated the due process guarantee of the Constitution. Id. pp 44-52. The United Mine Workers of America and other black lung advocates, including miners, intervened on behalf of the Secretary.

The District Court granted the NMA limited injunctive relief, but ultimately granted the Secretary's motion for summary judgment, upholding the regulations in every respect. Nat'l Mining Ass'n v. Chao, 160 F. Supp. 2d 47 (D.D.C. 2001) (Mem. Op.) [hereinafter "NMA"]. Rejecting the Secretary's argument that the District Court lacked jurisdiction, the court first found that it had jurisdiction pursuant to 28 U.S.C. s 1331, because NMA challenged a rulemaking, rather than an "order," of DOL. Id. at 54-56. Black lung benefits determinations ("orders") may be challenged only in the Court of Appeals. 33 U.S.C. s 921(c), (e).

The District Court next addressed NMA's claim that many of the rules were impermissibly retroactive, in part because they applied to pending claims as well as claims filed after the effective date of the regulations. See NMA, 160 F. Supp. 2d at 65. The court agreed with all parties that the Secretary was not authorized to promulgate retroactive regulations, but found that the challenged regulations were not retroactive, because some apply only to newly filed claims, while the remainder "simply clarify legal principles that were already in effect and [did] not change the substantive standards of entitlement." Id. Finally, the District Court upheld the regulations against the various substantive challenges. Id. at 69-90. Appellants now seek review of the District Court's determinations.

II. Discussion

A. Jurisdiction

The government challenged the District Court's jurisdiction to hear appellants' broad-scale attack on the Department's

regulations and reiterates that argument before us. It is the government's contention that the mining companies may only challenge the regulations piecemeal, insofar as particular provisions are brought into question, by an appeal directly to the Court of Appeals from a compensation order of the Benefits Review Board. That is so, according to the government, because the BLBA provides that a person "adversely affected or aggrieved by a final order of the Board may obtain review of that order in the United States court of appeals for the circuit in which the injury occurred ..." 33 U.S.C. s 921(c) (emphasis added).

The obvious difficulty with the government's position is that this provision putting exclusive review jurisdiction in the Court of Appeals speaks of orders, but Congress in passing the APA drew a distinction between orders, which typically follow adjudications, and regulations. See National Treasury Employees Union v. Weise, 100 F.3d 157, 160 (D.C. Cir. 1996) (explaining that courts and Congress use the terms "regulation" and "rule" interchangeably); compare 5 U.S.C. s 551(4) (defining "rule") with id. s 551(6) (defining "order"). Indeed, the BLBA itself indicates that Congress was using order in the same sense it used the term in the APA. The other provision the government points to, 33 U.S.C. s 921(e), states that "proceedings for suspending, setting aside, or enforcing a compensation order, whether rejecting a claim or making an award, shall not be instituted otherwise than as provided above" (referring to s 921(c) (emphasis added)). That language makes rather clear that in s 921(c) Congress used the term "order" to refer to an adjudicatory compensation order, not the promulgation of a regulation, and therefore the preclusion of review other than by s 921(c) would seem not to apply to review of a regulation. Since Congress was silent on how review of regulations was to be accomplished, it would appear accordingly that persons seeking such review would be directed by the APA to go to district court. See Workplace Health & Safety Council v. Reich, 56 F.3d 1465, 1467 (D.C. Cir. 1995).

In that regard, the Supreme Court's decision in McNary v. Haitian Refugee Center, Inc., 498 U.S. 479 (1991), instructs

us to read very carefully legislative restrictions on district court review of generic challenges to agency action. In the Immigration Reform and Control Act of 1986, Congress provided that there would be "no administrative or judicial review of a determination respecting an application for adjustment of status" except in accordance with that subsection, which eventually provided for judicial review in the Court of Appeals. 8 U.S.C. s 1160(e). The Court held that s 210(e) of the Reform Act did not deprive a district court of subject matter jurisdiction of "general collateral challenges to unconstitutional practices and policies used by the agency in processing applications." McNary, 498 U.S. at 492.

The Court read the phrase "determination respecting an application for adjustment of status" to refer only to an individual adjudication - not a determination made in a regulation. In our case, the word order is more obviously confined to an adjudication than the word determination, so therefore this case, linguistically, appears a fortiori to McNary.1 To be sure, the Court also observed that plaintiffs' challenge to the procedures would not easily be remedied by individual appeals to the Court of Appeals, a notion we return to below. Id. at 496.

The government points to another Supreme Court case, Thunder Basin Coal Company v. Reich, 510 U.S. 200 (1994), holding that the Federal Mine Safety and Health Act precluded district court jurisdiction over a pre-enforcement challenge to several Department of Labor regulations. In that case, a

¹ The Second Circuit has also recognized that the term "order" carries a limited meaning. In Merritt v. Shuttle, Inc., 187 F.3d 263 (2d Cir. 1999) (Merritt I), that court held that Merritt could not bring a Bivens claim challenging an FAA order suspending his pilot's certificate because 49 U.S.C. s 46110(a) vested review of an FAA "order" in the Court of Appeals and his Bivens claim challenged the merits of the administrative adjudication. By contrast, in Merritt v. Shuttle, Inc., 245 F.3d 182, 188 (2d Cir. 2001) (Merritt II), the Second Circuit clarified that s 46110(a), which referred only to an FAA order, did not preclude district court jurisdiction over Merritt's FTCA claim, which did not claim that he was either injured or aggrieved by the order suspending his license.

mine operator refused to post the names of two United Mine Workers of America employees - not employees of the mine operator - who had been chosen by its employees as their representatives to "walk around" with federal inspectors. The Mine Safety statute authorized the Secretary of Labor to seek enforcement of the posting in proceedings before the Federal Mine Safety and Health Review Commission. Before the Secretary could do so, the mine operator, claiming rights under both the National Labor Relations Act and the Constitution, sought an injunction against the Labor Department's position that the mine operator was obliged to post the The Court held that the District Court lacked jurisdiction over "such" a pre-enforcement challenge in light of the comprehensive administrative and judicial review procedures culminating in the Court of Appeals. Id. at 208. Although the statute was silent on pre-enforcement review, this sort of case was thought to be implicitly precluded. The company had simply jumped the gun by suing before the Secretary issued a citation, and the company's argument that both the Constitution and the National Labor Relations Act allowed it to exclude non-employee representatives could be meaningfully reviewed in the Court of Appeals. It is important to note that the case did not involve a regulation, which is typically treated differently from an adjudication. United States v. Florida East Coast Ry. Co., 410 U.S. 810, 820-21 (1973). Indeed, under the Mine Safety Act safety standards are issued as regulations and are explicitly reviewable in the Court of Appeals. 30 U.S.C. s 811(d).2

The government also relies on two circuit court cases, Compensation Dep't of Dist. Five v. Marshall, 667 F.2d 336, 340-44 (3d Cir. 1981), and Louisville & Nashville R.R. v. Donovan, 713 F.2d 1243, 1245-47 (6th Cir. 1983), denying preenforcement review under this very statute. The first of these, upon which the second relies, involved a request for an injunction brought by the United Mine Workers against the

² The Court did not indicate how it would treat the review of a regulation that was not a safety standard. Compare Chamber of Commerce of the United States v. Dep't of Labor, 174 F.3d 206 (D.C. Cir. 1999), with id. at 213 (Silberman, J., dissenting).

Labor Department to prevent the Secretary from independently examining x-rays presented by those seeking eligibility for black lung benefits. The statute obliged the Secretary to accept a radiologist's interpretation of an x-ray if certain requirements were met. The Secretary's position was that although his Office of Workers' Compensation was bound, neither an ALJ nor the independent Benefits Review Board was so bound, and therefore nothing prevented the Secretary from turning over a competing interpretation to the mine operator to be used as rebuttal evidence.

The Third Circuit held that the District Court lacked jurisdiction because the "scheme of review" established by Congress "for determination of black lung benefits" was exclusive; it provided administrative review and then review in the Court of Appeals. There was no reason why the United Mine Workers could not challenge the Secretary's enforcement policy in an individual adjudication before the Benefits Review Board and, if necessary, in the Court of Appeals. The case therefore bears a strong resemblance to Thunder Basin; a plaintiff sought to short-circuit the administrative process by challenging a Department enforcement position in a district court. Compare Compensation Department, 667 F.2d at 340, with Thunder Basin, 510 U.S. at 216.

The Sixth Circuit's Louisville & Nashville R.R. case is somewhat more problematic. There, fifteen railroads sought and gained an injunction in district court preventing the Secretary from extending coverage of the BLBA to railroad employees. The Department of Labor had issued guidelines defining the statutory term "transportation of coal" to include railroad employees if they were transporting coal between the extraction site and the tipple and if their work was necessary to the extraction process. The Sixth Circuit reversed, following the Third Circuit's analysis in Compensation Department, pointing out that any railroad could contest the Secretary's position before the Benefits Review Board, and if necessary challenge an order awarding benefits in the Court of Appeals. Although the guidelines involved seem a bit more generic than the enforcement policies implicated in either Thunder Basin or Compensation Department, the Secretary had not

issued a formal regulation, as is true in our case, and again as in Compensation Department, 667 F.2d at 334, there was no reason to believe that a railroad's legal position, if correct, could not be fully remedied through review in the Court of Appeals. Louisville & Nashville RR, 713 F.2d at 1246-47.3

In the case at bar the Secretary of Labor has chosen, as was not true in any of the cases upon which the government relies, to gain all of the law-declaring attributes of an APA notice-and-comment rulemaking. Trans-Pacific Freight Conference of Japan/Korea v. Federal Maritime Comm'n, 650 F.2d 1235, 1244-45 (D.C. Cir. 1980) (distinguishing noticeand-comment rulemaking, which is "prospective in operation and general in scope, " from adjudications). Accordingly, the cases upon which she relies do not really support her position. Moreover, the regulations before us are challenged primarily on the ground that they are impermissibly retroactive. To determine whether that is true it is necessary to analyze carefully all of the regulations together as well as the entire rulemaking process, which would not be feasible in individual adjudications dealing with particular regulatory provisions. Cf. Kreschollek v. Southern Stevedoring Co., 78 F.3d 868 (3d Cir. 1996) (holding that 33 U.S.C. s 921 did not deprive a district court of jurisdiction over plaintiff's constitutional claim as to the lack of a pre-deprivation hearing because the statutory review process would be insufficient to provide him with the full relief to which he might be entitled). In that respect, this case is closer to McNary than Thunder Basin. As such, the District Court did have jurisdiction over appellants' challenges, to which we now turn.

B. Retroactivity

Appellants argue that some of the provisions in the new regulations are impermissibly retroactive. In particular, ap-

³ The Seventh Circuit, by contrast, has explained that even "an order denying or revoking a certificate of exemption, not being a compensation order, would not be subject to the special review procedure established by 33 U.S.C. s 921." Maxon Marine, Inc. v. Director, Office of Workers' Compensation Programs, 39 F.3d 144, 146 (7th Cir. 1994).

pellants cite the following rules: ss 718.104(d), 718.201(a)(2), 718.201(c), 718.204(a), 725.101(a)(6), 725.101(a)(31), 725.204, 725.212(b), 725.213(c), 725.214(d), 725.219(c), 725.219(d), 725.309(d), and 725.701. We will address each rule in turn.

1. Legal Principles Governing Retroactivity

The general legal principles governing retroactivity are relatively easy to state, although not as easy to apply. An agency may not promulgate retroactive rules absent express congressional authority. Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988). A provision operates retroactively when it "impair[s] rights a party possessed when he acted, increase[s] a party's liability for past conduct, or impose[s] new duties with respect to transactions already completed." Landgraf v. USI Film Prods., 511 U.S. 244, 280 (1994). In the administrative context, a rule is retroactive if it " 'takes away or impairs vested rights acquired under existing law, or creates a new obligation, imposes a new duty, or attaches a new disability in respect to transactions or considerations already past.' " Nat'l Mining Ass'n v. United States Dep't of Interior, 177 F.3d 1, 8 (D.C. Cir. 1999) (quoting Ass'n of Accredited Cosmetology Sch. v. Alexander, 979 F.2d 859, 864 (D.C. Cir. 1992)). The critical question is whether a challenged rule establishes an interpretation that "changes the legal landscape." Id. (quoting Health Ins. Ass'n of Am., Inc. v. Shalala, 23 F.3d 412, 423 (D.C. Cir. 1994)). It is undisputed here that the Secretary was not authorized to promulgate retroactive rules governing BLBA benefits determinations. Hence, the parties dispute only whether the challenged regulations are retroactive.

The Secretary argues that none of the rules is retroactive, even as applied to pending claims, because all are merely procedural and do not confer new substantive rights or liabilities. See Landgraf, 511 U.S. at 275 ("Changes in procedural rules may often be applied in suits arising before their enactment without raising concerns about retroactivity."). It is true that purely procedural rules often do not operate retroactively even when applied to transactions predating their institution. This is because such rules often regulate

only "secondary rather than primary conduct." Id. Where a "procedural" rule changes the legal landscape in a way that affects substantive liability determinations, however, it may operate retroactively. See Martin v. Hadix, 527 U.S. 343, 359 (1999) (noting that, in Landgraf, the Court "took pains to dispel the 'suggest[ion] that concerns about retroactivity have no application to procedural rules' ") (quoting Landgraf, 511 U.S. at 275 n.29).

Rather than rely on "procedural" and "substantive" labels, a court must "ask whether the [regulation] operates retroactively." Id. This inquiry involves a "commonsense, functional judgment about 'whether the new provision attaches new legal consequences to events completed before its enactment.' " Id. at 357-58 (quoting Landgraf, 511 U.S. at 270). Thus, where a rule "changes the law in a way that adversely affects [a party's] prospects for success on the merits of the claim," it may operate retroactively even if designated "procedural" by the Secretary. Ibrahim v. District of Columbia, 208 F.3d 1032, 1036 (D.C. Cir. 2000).

The Secretary argues, and the District Court agreed, that none of the challenged rules changes the landscape, because the rules merely clarify the Secretary's position or conform to cases decided by the Courts of Appeals. In analyzing each new regulation, we first look to see whether it effects a substantive change from the agency's prior regulation or practice. If a new regulation is substantively consistent with prior regulations or prior agency practices, and has been accepted by all Courts of Appeals to consider the issue, then its application to pending cases has no retroactive effect. If a new regulation is substantively inconsistent with a prior regulation, prior agency practice, or any Court of Appeals decision rejecting a prior regulation or agency practice, it is retroactive as applied to pending claims.

Some of the challenged rules here codify the results of a case in one circuit while effectively reversing a case in another circuit in which the court rejected the Secretary's practice or policy. Such rules change the legal landscape as applied to cases that were pending when the regulations were

promulgated. See National Mining, 177 F.3d at 8 (explaining that "[w]here before there was 'a range of possible interpretations, ' " of the relevant statutes, a rule may establish " 'a precise interpretation' " that changes the legal landscape) (citing Health Ins. Ass'n, 23 F.3d at 423-24). It goes without saying that such rules change the law for cases pending in the circuit that previously rejected the Secretary's approach. In those cases, the operators insured against the filed claims based on the law in effect at the time the claims were filed. Less obviously, the regulations preclude the courts in other circuits from adopting the view of their sister court rejecting the Secretary's position, a possibility that was still available when the cases were initially filed. Thus, to the extent that a new rule reflects a substantive change from the position taken by any of the Courts of Appeals and is likely to increase liability, that rule is impermissibly retroactive as applied to pending claims.

2. Application of Legal Principles to Challenged Rules

We find some of the challenged rules to be impermissibly retroactive as applied to claims that were pending on the regulations' effective date. None of the new regulations is retroactive as to claims filed on or after the effective date. The distinction between pending and newly filed claims is one on which appellants rely in their briefs. See Br. for Appellants at 15 n.6 (stating that the relevant date for purposes of retroactivity is the date the claim is filed, as that is the last date on which the operators' and insurers' transactions are closed and expectations are settled); Reply Br. for Appellants at 4 (arguing that the Secretary "fails to explain why key provisions are expressly made retroactively applicable to pending and previously filed claims," while saying nothing about claims filed after the effective date). Moreover, NMA never affirmatively argues that the rules should be considered retroactive as applied to claims first filed after the effective date. Nor would the record support such an argument.

Appellants do argue that the regulations are retroactive as applied to newly filed claims when those claims are "subsequent claims." We reject this argument. Under both the

new and old regulations, a miner whose claim is initially denied may later file a new claim if he subsequently develops black lung disease or can show that another condition of entitlement has changed. See 20 C.F.R. s 725.309(d). As we explain in more detail below, a claimant bringing such a claim still bears the burden of demonstrating that he meets all of the relevant conditions. For this reason, we agree with the Secretary that such claims are new claims to which the application of the new regulations is permissible.

20 C.F.R. s 718.104(d): The "treating physician rule" instructs the officer adjudicating a miner's claim to consider the relationship between the miner and any treating physician whose report is submitted when determining whether the miner suffers from black lung disease and whether he was totally disabled or died because of the disease. The disputed rule instructs the officer to consider the nature of the relationship (a doctor's opinion is entitled to more weight if he has treated the miner for pulmonary, as opposed to nonpulmonary, conditions), its duration, the frequency of treatment, and the extent of treatment in weighing the doctor's opinion along with the other evidence. 20 C.F.R. s 718.104(d)(1)-(4). The regulation provides that in "appropriate cases, " the doctor-patient relationship "may constitute substantial evidence in support of the adjudication officer's decision to give that physician's opinion controlling weight," but only when the weight given is based on the credibility of that physician's opinion "in light of its reasoning and documentation, other relevant evidence and the record as a whole." Id. s 718.104(d)(5) (emphasis added). It applies both to pending claims and claims filed after the regulations' effective date. See id. ss 718.2, 725.4(a) (setting forth the applicability of the regulations in Part 718). The old rule said nothing about the relationship between the miner and the evaluating doctor. See 20 C.F.R. s 718.104 (2000).

We hold that treating physician rule is not retroactive, because it codifies judicial precedent and does not work a substantive change in the law. NMA argues that the rule contravenes a number of court decisions. This argument is unfounded. The consensus among courts has been that an

agency adjudicator may give weight to the treating physician's opinion when doing so makes sense in light of the evidence and the record, but may not mechanistically credit the treating physician solely because of his relationship with the claimant. For example, in Peabody Coal Co. v. McCandless, 255 F.3d 465, 469 (7th Cir. 2001), relied upon by NMA, the Seventh Circuit restated its disapproval of "any mechanical rule that the views of a treating physician prevail" (citing Consolidation Coal Co. v. OWCP, 54 F.3d 434, 438 (7th Cir. 1995)). Instead, the Seventh Circuit has repeatedly demanded that the adjudicator explain his or her decision to credit the treating physician in terms of "a medical reason," id., or explain why the opinion of the treating physician was viewed to be "better reasoned" than the opinions of non-treating physicians, Consolidation Coal Co., 54 F.3d at 438; see also Amax Coal Co. v. Beasley, 957 F.2d 324, 327 (7th Cir. 1992) (holding, in a case where both doctors agreed that coal exposure probably had not caused the miner's death, that an ALJ may not disregard uncontradicted medical evidence nor give more weight to the examining physician "solely because that doctor personally treated the claimant") (emphasis in original). These holdings are codified in the new s 718.104(d), which by its terms allows an adjudicator to give weight to the treating physician's opinion only when that decision is supported by the opinion's "reasoning and documentation" in light of the other evidence in the record. 20 C.F.R. s 718.104(d)(5).

The other cases cited by appellants similarly express the principles embodied in the new rule. In Sterling Smokeless Coal Co. v. Akers, 131 F.3d 438, 441 (4th Cir. 1997), the Fourth Circuit vacated an award of benefits where the ALJ had "mechanistically credited, to the exclusion of all other testimony," the opinions of two examining physicians who had only treated the miner for a month, despite allegations that the two doctors had not independently evaluated the miner themselves. The court acknowledged that the opinions of treating physicians can be "deserv[ing of] especial consideration," but rejected any requirement or presumption that their opinions automatically be given greater weight. Id.

(quoting Grizzle v. Pickands Mather & Co., 994 F.2d 1093, 1097 (4th Cir. 1993)).

Likewise, the Sixth Circuit recently summarized its law in Peabody Coal Co. v. Groves, 277 F.3d 829 (6th Cir. 2002). Reviewing past cases, the court explained that opinions of treating physicians are entitled to greater weight, but should not "automatically be presumed to be correct"; rather, "their opinions should be 'properly credited and weighed.' " Id. at 834 (quoting Tussey v. Island Creek Coal Co., 982 F.2d 1036, 1042 (6th Cir. 1993)). Adjudicators must "examine the medical opinions of treating physicians on their merits and ... make a reasoned judgment about their credibility." Id.; accord Griffith v. Director, OWCP, 49 F.3d 184, 186-87 (6th Cir. 1995) (holding that an ALJ was not required to give greater weight to the opinion of the treating physician where the physician was equivocal as to the cause of the miner's disease).

In short, appellants do not cite a single case from any circuit in which a Court of Appeals espoused principles at odds with the new rule embodied in s 718.104(d). As the cases demonstrate, the courts to consider the issue have adopted the balanced policy reflected in the new rule. Thus, the rule does not upset settled expectations, and it is not retroactive as applied to pending claims for benefits.

20 C.F.R. s 718.201(a)(2): NMA argues that the new rule in s 718.201(a), which defines pneumoconiosis, is impermissibly retroactive. Section 718.201(a) parrots the statutory definition of pneumoconiosis, i.e., "a chronic dust disease of the lung and its sequelae, including respiratory and pulmonary impairments, arising out of coal mine employment." See 30 U.S.C. s 902(b). The regulation goes on to define pneumoconiosis as including both medical or "clinical" pneumoconiosis and statutory or "legal" pneumoconiosis. 20 C.F.R. s 718.201(a). Legal pneumoconiosis is defined to include "any chronic lung disease or impairment ... arising out of coal mine employment," including "any chronic restrictive or obstructive pulmonary disease arising out of coal mine employment." Id. s 718.201(a)(2).

NMA challenges as retroactive the inclusion of restrictive or obstructive pulmonary disease in the definition of pneumoconiosis. It argues that most courts require individual miners to prove the causal relationship between mining and their obstructive lung disease, and that the new rule will change this. This argument is misplaced. NMA concedes that the record supports the premise that obstructive lung disease may be caused by mining exposure and can contribute to a miner's disability. Br. for Appellants at 17 n.8. The new rule does no more than reflect this reality. It does not, as appellants suggest, create a presumption that all or even most obstructive disease is caused by exposure to coal dust. The District Court correctly found that, under both the old and new regulations, "each miner bear[s] the burden of proving that his obstructive lung disease did in fact arise out of his coal mine employment." NMA, 160 F. Supp. 2d at 79 (quoting 65 Fed. Reg. at 79,938) (emphasis added).

NMA also alleges that the preamble to the regulations impermissibly suggests that an adjudicator may ignore a medical report if the reporting doctor concludes that a miner's obstructive lung disease was caused by smoking, rather than mining. This objection is entirely meritless. The regulation's plain text in no way indicates that medical reports will be excluded if they conclude that a particular miner's obstructive disease was caused by smoking, rather than mining. Indeed, the preamble itself states that the revised definition does not alter the requirement that individual miners must demonstrate that their obstructive lung disease arose out of their work in the mines. See 65 Fed. Reg. at 79,938. And appellants acknowledge that this regulatory statement is acceptable. Br. for Appellants at 17 n.8. To the extent that appellants' objection is based on anticipated misapplications of the rule by agency adjudicators, it is unripe for review. Appellants may object to applications of the rule only in the context of concrete cases.

20 C.F.R. s 718.201(c), 725.309(d): Section 718.201(c) states that pneumoconiosis is "recognized as a latent and progressive disease which may first become detectable only after the cessation of coal mine dust exposure." Appellants argue that

this regulatory statement is impermissibly retroactive, because the question whether pneumoconiosis is latent and progressive is unsettled. This contention is based on a false reading of the rule.

Appellants acknowledge that at least one rare type of pneumoconiosis is both latent and progressive, but argue that the more common "simple pneumoconiosis" is not. Br. for Appellants at 17. During oral argument, the Secretary conceded that the most common forms of pneumoconiosis are not latent. Moreover, the Secretary acknowledged that latent and progressive pneumoconiosis is rare, occurring in a small percentage of cases by all accounts. Tr. of Oral Arg. at 52-55. Nothing in the disputed rule says otherwise. The rule simply prevents operators from claiming that pneumoconiosis is never latent and progressive. The medical literature makes it clear that pneumoconiosis may be latent and progressive, and appellants do not dispute this point.

NMA's concern about the definition of pneumoconiosis as latent and progressive is tied to the fact that, under 20 C.F.R. s 725.309(d), a claimant whose claim was previously denied may file a subsequent claim. The subsequent claim will be denied unless the claimant demonstrates that one of the applicable conditions of entitlement has changed since the claim was denied. Id. The "applicable condition" must be one of the conditions on which the claim was denied in the first place. Id. s 725.309(d)(2). Thus, a miner who was originally found not to suffer from black lung disease may file again if he develops the disease subsequently. Any such claimant, however, must still prove that he now has pneumoconiosis and that his disease arose out of employment in coal mines.

On its own, s 725.309(d) is not retroactive. First, it applies only to claims filed after the regulations' effective date and has no application to pending subsequent claims. See id. s 725.2(c). In any event, the new regulation, in relevant part, mirrors the prior s 725.309(d), which provided that a subsequent claim will be denied unless the deputy commissioner determines that "there has been a material change in condi-

tions." 20 C.F.R. s 725.309(d) (2000). Counsel acknowledged at oral argument that, under the old regulatory regime, a claimant who had been denied benefits could reapply when relevant conditions changed. Tr. of Oral Arg. at 39. The new rule does not allow anything more. Because it is not substantively new, it does not change the legal landscape.

Nor is s 725.309(d) retroactive in combination with the rule recognizing that pneumoconiosis can be latent and progressive. While appellants express concern that the regulations allow claimants to relitigate old claims under an irrebuttable presumption that the miners' pneumoconiosis is progressive, the rules afford no such presumption. The fundamental requirement that the claimant must prove a change in a relevant condition (such as whether he developed pneumoconiosis after his claim was denied) has not changed. A miner will only be successful in his subsequent claim if he has actually developed pneumoconiosis or another relevant condition of entitlement in the interim.

20 C.F.R. s 718.204(a): The "total disability rule" provides that nonpulmonary diseases that "cause[] an independent disability unrelated to the miner's pulmonary or respiratory disability, shall not be considered in determining whether a miner is totally disabled due to pneumoconiosis." The contested language does not appear in the prior version of the regulation. We find that the rule is retroactive as applied to pending cases, because it changes the legal landscape in a way that is likely to affect liability determinations.

NMA contends that the rule's purpose and effect is to overrule a Seventh Circuit decision in Peabody Coal Co. v. Vigna, 22 F.3d 1388 (7th Cir. 1994). The record supports this suggestion. See 62 Fed. Reg. at 3344-45 (stating that the new regulation "makes clear the Department's disagreement with the holding in [Vigna]" and was "designed to ensure that the Seventh Circuit's view will not be applied outside that circuit to cases arising under part 718"). The District Court held that the regulation codified existing law and the Secretary's prior interpretation. NMA, 160 F. Supp. 2d at 67-68 (citing many cases and adding a "But see" citation to Vigna).

In Vigna, a miner who had mined for forty years suffered a stroke and became totally disabled. 22 F.3d at 1390. The miner was also a longtime smoker. Id. The Seventh Circuit held, contrary to the ALJ's finding, that the coal company successfully rebutted the presumption that the miner's disability arose from his coal mine employment. Id. at 1394. The court found that the evidence left no doubt that the miner's employment did not contribute to his stroke, which was the cause of his total disability. Id. At the time of the stroke, there was no evidence that the miner had pneumoconiosis. Id.

Under the new rule, the adjudicator would not be able to consider a nonpulmonary condition (such as a stroke) at all in determining whether the miner was totally disabled due to pneumoconiosis. Instead, the adjudicator would have to determine whether the miner was totally disabled due to pneumoconiosis without considering his unrelated, nonpulmonary disability. The new regulation thus changes the legal landscape by precluding adjudicators from considering unrelated medical disabilities, reversing the rule in the Seventh Circuit, and precluding any other circuit from adopting the Seventh Circuit's interpretation. It cannot be said to be merely "procedural," because it has a direct effect on the determination of liability.

In finding the rule to be impermissibly retroactive as applied to pending cases, we do not, of course, intend to affect the law in circuits that have adopted or might adopt positions that conform with the Secretary's interpretation. See, e.g., Cross Mountain Coal, Inc. v. Ward, 93 F.3d 211, 217 (6th Cir. 1996) (holding that "the fact that claimant may, or may not, also be disabled by a back injury is not grounds for denying his claim for benefits"). Instead, the effect of our ruling is to leave the state of the law on this question exactly as it was prior to the regulations' promulgation for cases that had already been filed when the regulations were promulgated.

20 C.F.R. s 725.701: The rule embodied in s 725.701 creates a rebuttable presumption that when a miner who is eligible for black lung benefits receives medical treatment for

a pulmonary disorder, the disorder is "caused or aggravated by the miner's pneumoconiosis." 20 C.F.R. s 725.701(e). The employer may rebut the presumption with "credible evidence that the medical service or supply provided was for a pulmonary disorder apart from those previously associated with the miner's disability" or was beyond the treatment necessary to treat the covered disorder, or "was not for a pulmonary disorder at all." Id. The regulation codifies the so-called Doris Coal presumption, named for a Fourth Circuit case that adopted the presumption before it was included in the new regulations. See Doris Coal Co. v. Director, OWCP, 938 F.2d 492, 496-97 (4th Cir. 1991) ("Since most pulmonary disorders are going to be related or at least aggravated by the presence of pneumoconiosis, when a miner receives treatment for a pulmonary disorder, a presumption arises that the disorder was caused or at least aggravated by the miner's pneumoconiosis, making the employer liable for the medical costs."). The Fourth Circuit later reaffirmed and clarified the presumption, using language that was mirrored in the new regulation. See Gulf & W. Indus. v. Ling, 176 F.3d 226, 233 (4th Cir. 1999) (holding that the employer can rebut the presumption by producing "credible evidence that the treatment rendered is for a pulmonary disorder apart from those previously associated with the miner's disability, or is beyond that necessary to effectively treat a covered disorder, or is not for a pulmonary disorder at all").

NMA argues that the regulation codifying the judicial presumption is retroactive as applied to pending cases, and we agree. The rule is not reflected in the prior regulation, even though it may reflect the Secretary's longstanding policy. See Doris Coal, 938 F.2d at 496-97. Moreover, the rule contradicts the Sixth Circuit's holding in Glen Coal Co. v. Seals, 147 F.3d 502 (6th Cir. 1998). In that case, the court held that the Doris Coal presumption is permissible under the APA, because it only reallocates the burden of production, not the burden of proof. Id. at 512-13. Nonetheless, the court struck down the presumption as inconsistent with Sixth Circuit law, in part because it found that the creation of such judicial presumptions ran afoul of the BLBA's statutory goal

of uniformity. Id. at 513-14 (citing Director, OWCP v. Greenwich Collieries, 512 U.S. 267 (1994)). The regulation changes the outcome for cases that have already been filed in the Sixth Circuit and any other circuit that would have rejected Doris Coal. Our holding is, of course, not intended to affect the law in the Fourth Circuit or any other circuit that would have embraced the Doris Coal presumption. That judicial presumption remains the law in the circuits that adopt it. Our holding simply prevents the Secretary from imposing the presumption, in the form of a new regulation, on all of the other circuits for cases that were filed before the regulations were promulgated.

20 C.F.R. s 725.101(a)(6): The rule propounded in s 725.101(a)(6) defines "benefits" to include any expenses related to the medical examination and testing authorized pursuant to s 725.406, which requires the Department of Labor to provide each applicant for benefits with a pulmonary evaluation at no expense to the miner. The new s 725.101(a)(6) conforms the regulatory definition of "benefits" to s 725.406, both the old and new versions. The prior version of s 725.406(c) already provided that the cost of the medical examination would be paid by the Fund and that the Fund would be reimbursed "by an operator, if any, found liable for the payment of benefits to the claimant." 20 C.F.R. s 725.406(c) (2000). Likewise, the new s 725.406(e) provides that the cost of the medical examination will be paid by the Fund and that the Fund will be reimbursed "by an operator, if any, found liable for the payment of benefits to the claimant."

NMA argues that s 725.101(a)(6) retroactively shifts to the employer the cost of the medical examination provided under s 725.406. NMA recognizes that the cost always has been shifted under s 725.406 when an operator is found liable for the payment of benefits. Its challenge is based on the misperception that the new rule shifts the cost of the medical examination even when the miner does not prevail. This is incorrect. The cost shifts to the employer only when "benefits" are awarded. When no benefits are awarded, the cost of the examination presumably will continue to be paid by the

Fund, as set forth in s 725.406. Appellants have not pointed to anything in the new definition that departs from the system already in place under the old s 725.406(c). Thus, the new definition changes nothing and is not impermissibly retroactive.

20 C.F.R. s 725.101(a)(31): The rule in s 725.101(a)(31) provides that "[a] payment funded wholly out of general revenues shall not be considered a payment under a workers' compensation law." This provision is significant because the benefits payable under the BLBA must be offset by any amount the miner receives for his black lung disability under a state or federal workers' compensation law. See 30 U.S.C. s 932(g). NMA agrees that the new rule reflects prior agency practice, but argues that it is nonetheless retroactive as applied to pending cases because at least one Court of Appeals has rejected the agency's practice. We agree.

In Director, OWCP v. Eastern Associated Coal Corp., 54 F.3d 141 (3d Cir. 1995), the Third Circuit declined to defer to the Director of the OWCP's policy of not reducing a miner's BLBA benefits by the amount that he received from general revenues under a state occupational disease compensation act. The court agreed that the statutory reference to "workers' compensation law" was ambiguous. However, the old regulation said nothing about payments funded out of general revenues, so the court declined to exclude workers' compensation payments funded out of general revenues. Id. at 147-49; 20 C.F.R. s 725.101(a)(4) (2000). The court suggested that the Secretary rewrite the regulations to achieve the agency's regulatory goal. Id. at 149. This is exactly what the Secretary did in promulgating 20 C.F.R. s 725.101(a)(31). It would be impermissibly retroactive, however, to apply the new regulation to claims that were already pending when the new regulation took effect. It would also be retroactive to apply the regulation to adjust the payments being made on settled or resolved claims. Of course, other circuits remain free to apply the Secretary's longstanding interpretation of the prior regulation to pending claims. The regulation is not impermissibly retroactive as applied to claims filed after the regulations' effective date.

20 C.F.R. ss 725.204, 725.212(b), 725.213(c), 725.214(d), 725.219(c), (d): These regulations, as applied to claims other than those filed after the regulations' effective date, are impermissibly retroactive, because they expand the scope of coverage by making more dependents and survivors eligible for benefits. For example, the new s 725.204 describes criteria for determining whether a claimant qualifies for augmented benefits as a miner's spouse. The new version of the regulation eliminates a provision in the prior version that essentially prevented a miner from having more than one qualifying spouse for purposes of augmented benefits. Compare 20 C.F.R. s 725.204(a)(4) with 20 C.F.R. s 725.204(d)(1) (2000). Similarly, under the new 20 C.F.R. s 725.212(b) and s 725.214(d), a miner could have more than one surviving spouse if he divorced and remarried during the pertinent period. Sections 725.209 and 725.219 address the determination of the miner's dependent children. Section 725.213(c) provides that a surviving spouse or surviving divorced spouse whose entitlement to benefits is terminated because she remarries may thereafter again become entitled to benefits, either by divorcing or through the death of her successor spouse.

The Secretary recognizes that the new definitions expand the scope of liability, but defends the expansion as necessary to conform to the 1990 amendments to the Social Security Act, portions of which are incorporated into the BLBA. See 30 U.S.C. s 902(a)(2), (e) (incorporating various Social Security Act definitions found at 42 U.S.C. s 416). The District Court agreed, holding that the revisions "bring the regulations into conformity with changes made by Congress in 1990 to the" Social Security Act's definitions of "dependent wife" and other key terms. NMA, 160 F. Supp. 2d at 69.

The Secretary's position as to the new provisions' application remains unclear. In its brief, the Secretary suggests that the expanded definitions apply to all BLBA claims filed after the 1990 amendments to the Social Security Act. Presumably, this could even affect payments made on claims that were finally adjudicated before the new regulations were promulgated. In a post-hearing chart submitted pursuant to

an order of this court, the Secretary stated that the provisions would apply to all claims pending on the new regulations' effective date, as well as to claims filed after that date, and to all benefit payments made after that date, including still-open claims filed on or after, or pending on, August 18, 1978. See also 20 C.F.R. s 725.2 (setting forth the applicability of the provisions).

In either case, we hold that it would be unlawfully retroactive to apply the definitions to any claims other than those filed on or after the regulations' effective date. Before the effective date, mine operators had no notice of the new definitions, for they were never incorporated in the old regulations. The Secretary and intervenors contend that the Secretary had changed the functional definitions as early as 1994 to conform with the 1990 Social Security Act amendments, by changing the Department of Labor's procedural manual. Tr. of Oral Arg. at 80-84. There are two problems with this argument. The first is that counsels' citation to the record does not bear out the claim. Counsel cited 65 Fed. Reg. 79,964 in support of the argument that the Secretary had already adopted these new definitions as far back as 1994. But the cited page states only that, since 1994, the Secretary's procedure manual has provided that when a surviving spouse and a surviving divorced spouse both qualify, each is entitled to full benefits. This citation does not address the other challenged regulations, such as those dealing with surviving children and those addressing surviving spouses who become ineligible and then become eligible again. The second problem is that the Secretary's prior practice was encapsulated only in a manual, not in a regulation promulgated pursuant to notice-and-comment rulemaking. There is nothing to indicate that the cited manual purported to state substantive rules or that it was generally known by and available to regulated parties. The Secretary cannot bind parties to substantive rules of which they had no notice.

The Secretary argues that application of the revised definitions to all claims filed after the 1990 amendment date is merely a correct application of the law in effect since that

time. The Secretary relies on Regions Hospital v. Shalala, 522 U.S. 448, 456 (1998), in which the Court held that the government's reaudit rule was not impermissibly retroactive because it merely called for the correct "application of the cost-reimbursement principles in effect" when the costs were incurred. By contrast, the instant regulations would actually change the scope of liability for claims that were filed at a time when these rules were not in effect. The decision in Regions Hospital does not support an argument that the Secretary may apply newly updated regulations retroactively to pending claims that were initiated before the change. Claims that have been resolved or settled, and claims that were filed after the effective date of the new rules, are not affected by this holding.

C. Substantive Challenges

In considering NMA's challenges to the revised regulations, we are guided by well-accepted principles of administrative law. To the extent NMA argues that the regulations conflict with the statute, we begin by asking whether "Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Chevron, U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 842 (1984). If, however, "the statute is silent or ambiguous with respect to the specific issue," we defer to the agency's reasonable construction of that statute. Id. at 843. As for NMA's arbitrary and capricious challenges, we will uphold the regulations as long as they "conform to certain minimal standards of rationality." Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 521 (D.C. Cir. 1983) (citation and internal quotation marks omitted). Though agencies have a duty of reasoned decisionmaking, see Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983), we "presume the validity of agency action," Kisser v. Cisneros, 14 F.3d 615, 618 (D.C. Cir. 1994), and may vacate only if the regulation is unsupported by substantial evidence, or if the agency has made a clear error in judgment, see Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 415-16 (1971).

We give particular deference to an agency's promulgation of evidentiary rules governing its own adjudications; the agency's defense of those regulations need only be "reasonable" so long as they are not "inconsistent with a federal statute," such as the APA. Chem. Mfrs. Ass'n v. Dep't of Transp., 105 F.3d 702, 706 (D.C. Cir. 1997). Finally, to the extent NMA argues that where, as here, we consider a challenge to a recently promulgated regulation, "[i]t is not uncommon ... that ... the meaning of the disputed provisions does not appear clearly until the case is before the courts of appeals. We typically accept the agency's construction - which often eliminates or narrows the dispute - because we recognize the agency is entitled to deference as to the meaning of its own regulation." Nat'l Mining Ass'n v. Babbitt, 172 F.3d 906, 911 (D.C. Cir. 1999). And in such cases, that construction may be expressed in the agency's brief or even at oral argument.

With these standards in mind, we consider each section of the revised regulations challenged by NMA.

Pneumoconiosis Definition

As revised, s 718.201(a) largely repeats the pneumoconiosis definition contained in the regulation's prior version but divides that definition into two groups, "clinical" pneumoconiosis ("those diseases recognized by the medical community as pneumoconiosis") and "legal" pneumoconiosis ("any chronic lung disease or impairment ... arising out of coal mine employment"). Compare 20 C.F.R. s 718.201 (2000) with 20 C.F.R. s 718.201(a) (2001). This revision merely adopts a distinction embraced by all six circuits to have considered the issue, see, e.g., Ling, 176 F.3d at 231-32; see also 65 Fed. Reg. at 79,938 (citing six circuit court cases), and, contrary to NMA's repeated assertions, neither "expand[s]" nor "redefine[s]" the meaning of pneumoconiosis beyond its statutory definition, Br. for Appellants at 38. Even if the regulation could be read to change the definition, the Black Lung Benefits Act broadly invests the Secretary with authority not only to write regulations defining "total disability," 30 U.S.C. s 902(f)(1) - which in turn depends on the definition of

pneumoconiosis - but also to supplement statutory terms "as [s]he deems necessary," id. s 932(a).

NMA also argues that another part of the pneumoconiosis definition, section 718.201(c), defining pneumoconiosis as a "latent and progressive disease which may first become detectable only after the cessation of coal mine dust exposure," lacks support in the administrative record and is thus arbitrary and capricious. In support of this argument, NMA points to record evidence indicating that pneumoconiosis is latent and progressive in - at most - eight percent of cases. See P.T. Donnan, et al., Progression of Simple Pneumoconiosis in Ex-Coalminers After Cessation of Exposure to Coalmine Dust iv (Inst. of Occupational Medicine, December 1997). We would thus sustain NMA's challenge to section 718.201(c) if the regulation said that pneumoconiosis is "always" or "typically" a latent and progressive disease. Although the regulation could be so read - "pneumoconiosis is recognized as a latent and progressive disease" - the remaining language provides that the disease "may first become detectable only after the cessation of coal mine dust exposure." The Secretary resolved this ambiguity at oral argument. Asked whether her "position is [that the] regulation simply states [pneumoconiosis] can be a progressive and latent disease," counsel answered "that's correct." Tr. of Oral Arg. at 54. In light of this narrowing construction, we conclude that the record evidence of the disease's latency and progressivity - which also includes a study (not explicitly relied on by the government in its brief) indicating that pneumoconiosis is latent and progressive as much as 24% of the time, see 62 Fed. Reg. 3338, 3344 (Jan. 22, 1997) (citing studies) - is sufficient to support section 718.201(c).

Change in Condition Rule

Revised s 725.309(d) governs the circumstances under which miners may file a claim after denial of an earlier claim. The prior regulation allowed such claims only upon proof of "a material change in conditions," 20 C.F.R. s 725.309(d) (2000), while the revised regulation requires "the claimant [to] demonstrate[] that one of the applicable conditions of entitle-

ment has changed, " 20 C.F.R. s 725.309(d) (2001). NMA's assertion that the revised rule is arbitrary and capricious because it "requires no exacting proof of materially changed conditions," Br. for Appellants at 40, and creates an "irrebuttable presumption" that a claimant has pneumoconiosis, id. at 46, finds no support in the regulation's language. The revised rule actually places the burden of proof squarely on the claimant to prove a change in condition, stating that "the claim shall be denied unless the claimant demonstrates that one of the applicable conditions of entitlement ... has changed." 20 C.F.R. s 725.309(d) (2001). Nor do we find convincing NMA's related argument that the revised regulation "waives res judicata or traditional notions of finality," Br. for Appellants at 45, as the Secretary has interpreted the regulation to permit new claims based only on the claimant's current condition and to preclude the admission of any evidence that existed at the time the previous claim was denied, see Br. for Appellees at 31.

Treating Physician Rule

A new rule, s 718.104(d) establishes that in determining whether a successful claimant's subsequent treatment for a pulmonary disorder is "compensable, the opinion of the miner's treating physician may be entitled to controlling weight." The rule is not mandatory. Instead, it permits ALJs to accord controlling weight to a treating physician's opinion if that opinion is "based on the credibility of the physician's opinion in light of its reasoning and documentation, other relevant evidence and the record as a whole." 20 C.F.R. s 718.104(d)(5).

According to NMA, the revised rule impermissibly shifts the burden of proof from claimant to employer. In support of this argument, NMA relies on Greenwich Collieries, where the Supreme Court held that absent specific statutory authorization, agencies may not informally create rules that supplant the APA's requirement that "the proponent of a rule or order has the burden of proof." 512 U.S. at 269-71 (quoting 5 U.S.C. s 556(d)). Greenwich Collieries, however, is inapplicable here, for neither the revised regulation's plain language

nor the Secretary's interpretation, see Br. for Appellees at 38, relieves claimants of the burden of proving both pneumoconiosis and the credibility of the doctor's opinion. Indeed, the Secretary points out that this regulation does not even "address which party bears the burden of proving the proposition to which the medical opinion evidence relates." Br. for Appellees at 38 (citing 65 Fed. Reg. at 79,933-34). Equally without merit is NMA's related argument that the treating physician rule is invalid because it "treats proof differently" by unfairly advantaging claimants' evidence; NMA even suggests that the rule enables doctors to help claimants obtain benefits fraudulently by "exaggerating" the extent of claimants' illnesses. Br. for Appellants at 34. This argument assumes that ALJs will automatically give controlling weight to treating physicians' opinions, yet the regulation actually places limits on their capacity to do so. See 20 C.F.R. s 718.104(d)(5) (permitting reliance on treating physician testimony only where physician's opinion is credible and consistent with record evidence). The requirement that a treating physician's opinion be credible, moreover, largely eliminates any risk of fraud.

Arguing that the treating physician rule is also arbitrary and capricious, NMA claims that "[t]here is no scientific or medical reason to conclude that a treating physician has clearer insight into any medical question that might arise in a black lung claim than a pulmonary specialist or any other doctor." Br. for Appellants at 35. In support of this argument, NMA cites record evidence suggesting that "there is a significant likelihood that a treating physician will use deception to assist patients in obtaining third party paid benefits." Cmts. of the Nat'l Mining Ass'n at 44 (1/6/2000), reprinted at J.A. 2231. Yet the agency considered and rejected this allegation, convincingly pointing out that the claim could "as easily be directed toward any party-affiliated physician, or group of such physicians, who may benefit by tailoring conclusions to fit the interests of the party paying for the medical opinion." 65 Fed. Reg. at 80,024; see also State Farm, 463 U.S. at 51-54 (holding that an agency's duty of reasoned

decisionmaking includes the requirement to explain away contrary evidence) and, e.g., id. at 52 ("Rescission of the [safety restraint] requirement would not be arbitrary and capricious merely because there was no evidence in direct support of the agency's conclusion.").

Hastening Death Rule

The Secretary revised s 718.205(c)(5) to state that "pneumoconiosis is a substantially contributing cause of a miner's death if it hastens the miner's death." Calling the rule arbitrary and capricious, NMA says "there is no science to support" a hastening death rule in the case of a death caused by a non-respiratory condition. Br. for Appellants at 50. The regulation, however, nowhere mandates the conclusion that pneumoconiosis be regarded as a hastening cause of death, but only describes circumstances under which a hastening-cause conclusion may be made. Moreover, it expressly requires claimants to prove that pneumoconiosis is the hastening cause. The fact that pneumoconiosis may, as NMA asserts, rarely or never hasten death primarily caused by other diseases does not undermine the regulation; it merely means that few or no claimants will succeed on the theory that black lung disease hastened death from other causes.

In any event, the record contains medical testimony indicating that "impairment of lung function from pneumoconiosis [can] weaken the body's defenses to infections and increase susceptibility to other disease processes." 65 Fed. Reg. at 79,950 (discussing testimony of Dr. Robert Cohen, Chief of the Division of Pulmonary Medicine, Cook County (IL) Hospital). Although NMA cites two medical studies suggesting contrary conclusions, see J.A. 1167, 2468, the Secretary considered this evidence and gave plausible reasons for rejecting it, noting that both studies focused on the narrower medical definition of pneumoconiosis rather than the broader legal one, and that one of the studies concluded only that hastening death was rare but "did not rule it out as a medical possibility," 65 Fed. Reg. at 79,951. In light of all this, we think it obvious that the Secretary has successfully discharged her duty of reasoned decisionmaking.

Operator Liability Rules

Section 725.408 establishes a deadline for coal mine operators to submit evidence if they disagree with their designation as parties potentially liable for a miner's claim, while s 725.495(c) provides that once an operator has been determined to be responsible for a claim, that operator may be relieved of liability only if it proves both that it is financially incapable of assuming liability and that another operator that more recently employed the miner is financially capable of doing so. Again relying on Greenwich Collieries, NMA argues that the revised rules "relieve the agency of its normal burden to identify the correct responsible party" and shift that burden onto coal mine operators in violation of the APA's requirement that proponents of an order sustain the burden of proof. Br. for Appellants at 62. NMA misreads both revised regulations. Section 725.408 shifts the burden of production, not the burden of proof; it requires nothing more than that operators must submit evidence rebutting an assertion of liability within a given period of time. Greenwich Collieries carefully distinguishes agency regulations that shift the burden of proof (prohibited by the APA "except as otherwise provided by statute, " 5 U.S.C. s 556(d)) from regulations that shift the burden of production (which the APA does not prohibit, see 512 U.S. at 270-80 (distinguishing burden of proof from burden of production)). NMA argues that s 725.495(c) nevertheless violates Greenwich Collieries because it "reliev[es] the agency of its natural burden of proving the identity of the correct responsible party." Br. for Appellants at 64. The regulation, however, shifts the burden of proof only to the "designated responsible operator," 20C.F.R. s 725.495(c); i.e., it applies only to the extent that a claimant has already carried his burden of proving that an operator is liable. "In seeking to be excused from liability," the District Court explained, "the operator becomes the 'proponent' of a remedial order of the ALJ and, therefore, the party to which [the APA] assigns the burden of proof." Mining Ass'n v. Sec'y of Labor, No. 00-3086, slip op. at 52 (D.D.C. Aug. 9, 2001); see also Greenwich Collieries, 512 U.S. at 278.

NMA argues that s 725.495(c) is also arbitrary and capricious because it rests on the premise that "employers and carriers are better situated to identify and prove an alternative liable party." Br. for Appellants at 64. As the Secretary points out, however, s 725.495(c) is not based on that presumption. See 65 Fed. Reg. at 80,008-09 (discussing s 725.495(c) but nowhere mentioning the rationale that mine operators and insurance carriers have superior access to information about miners' subsequent employment). Although the Secretary offers little in the way of positive support for the rule, s 725.495(c) - an evidentiary rule - need only be "reasonable" and not "inconsistent with a federal statute" to survive review. Chem. Mfrs. Ass'n, 105 F.3d at 706. Where, as here, the Secretary affords a mine operator liable for a claimant's black lung disease the opportunity to shift liability to another party, it is hardly irrational to require the operator to bear the burden of proving that the other party is in fact liable.

Medical Benefits Rule

The Secretary's revision of s 725.201(e) creates a presumption that any pulmonary disorder for which a miner receives treatment after successfully filing a BLBA claim is caused by that miner's pneumoconiosis. The new regulation allows the operator to rebut this presumption with credible evidence that the disorder was not pulmonary, the disorder was unrelated to the miner's pneumoconiosis, or the treatment the miner received was unnecessary.

Claiming that the medical benefits rule "shifts the burden to the employer to disprove medical coverage," Br. for Appellants at 52, NMA argues it too runs afoul of Greenwich Colleries. Although the regulation could be so read, the Secretary explains that it shifts only the burden of production to operators to produce evidence that the treated disease was unrelated to the miner's pneumoconiosis; the ultimate burden of proof remains on claimants at all times. See 65 Fed. Reg. at 80,022 (explaining that "invocation" of the presumption "shifts only the burden of production, not persuasion"); see also Ling, 176 F.3d at 233-34 (holding that an

identical "presumption merely reallocates the burden of production, and does not affect the burden of proof"); Seals, 147 F.3d at 512 (same).

NMA argues that the medical benefits rule is also arbitrary and capricious, pointing to a comment claiming that "[w]hen a miner receives a medical service or supply for a pulmonary disorder, it is not reasonable to assume that the disorder is caused or aggravated by pneumoconiosis." Cmts. of Gregory J. Fino, M.D., and Barbara J. Bahl, Ph.D. at 11 (1/4/2000), reprinted at J.A. 2439. Carefully considering this comment, however, the Secretary rejected it because the comment failed to distinguish between medical pneumoconiosis and the much broader legal definition of the disease. See 65 Fed. Reg. at 80,023. As the Secretary points out, there is a clear rational relationship between the fact proved (that a miner suffered from totally disabling pneumoconiosis in the past) and the fact presumed (that the miner's treated pulmonary disorder is related to that pneumoconiosis); this suffices for purposes of our review.

Total Disability Rule

An entirely new provision, s 718.204(a) states that "any nonpulmonary or nonrespiratory condition or disease, which causes an independent disability unrelated to the miner's pulmonary or respiratory disability, shall not be considered" in determining a miner's total disability under the BLBA. According to NMA, the rule runs counter to the proposition that parties may submit all relevant evidence in support of their position. See 30 U.S.C. s 923(b). This argument, however, ignores the BLBA's clear grant of authority to the Secretary to establish the medical criteria for adequate proof of "total disability." Id. s 902(f)(1)(D). And contrary to NMA's claim that "DOL's rule excludes relevant evidence for no good reason," Br. for Appellants at 48, we see an obvious rational basis for the rule: the statute only pertains to whether a miner is disabled "due to pneumoconiosis," and evidence of nonpulmonary conditions has no relevance to that inquiry. Indeed, three circuits have adopted just this reading of the Act. See 65 Fed. Reg. at 79,947 (citing cases from

Sixth, Seventh, and Tenth Circuits). But see Vigna, 22 F.3d at 1394-95.

Challenging the total disability rule as arbitrary and capricious, NMA claims that the regulation "is supported only by an intent to reverse" the Seventh Circuit's decision in Peabody Coal v. Vigna, which held that a miner totally disabled due to a nonpulmonary ailment could not be compensated under the Black Lung Benefits Act. See id. NMA's assertion regarding intent is irrelevant: no authority supports the proposition that a rule is arbitrary and capricious merely because it abrogates a circuit court decision. Quite to the contrary, "regulations promulgated to clarify disputed interpretations of a regulation are to be encouraged. Tidying-up a conflict in the circuits with a clarifying regulation permits a nationally uniform rule without the need for the Supreme Court to essay the meaning of every debatable regulation." Pope v. Shalala, 998 F.2d 473, 486 (7th Cir. 1999) (citation and internal quotation marks omitted).

NMA also claims that the total disability rule "is contrary to all of the medical testimony," Br. for Appellants at 49, but points only to record evidence generally indicating that evidentiary restrictions are "inconsistent with good medical practice," Cmts. of Drs. Fino and Bahl at 4, reprinted in J.A. 2432, evidence far too vague to supply any basis for concluding that the total disability rule is arbitrary and capricious. The revised regulation has a rational basis and is consistent with the APA; that is enough.

Evidence Limitation Rules

NMA next argues that nothing in the APA authorizes the revised regulations (ss 725.310(b), 725.414, 725.456, 725.457(d), and 725.458) setting limits on the amount and timing of evidence admissible in benefits determinations, because that statute "authorizes each party to submit whatever evidence that party thinks is needed to prove its case or defense." Br. for Appellants at 56. NMA's theory - that the APA permits introduction of unlimited amounts of evidence - is flatly contradicted by the statute itself, which empowers agencies to "exclu[de] ... irrelevant, immaterial, or unduly

repetitious evidence" as "a matter of policy," 5 U.S.C. s 556(d), as well as the Black Lung Benefits Act, which authorizes the Secretary to issue regulations "provid[ing] for the nature and extent of the proofs and evidence and the method of taking and furnishing the same in order to establish the rights to benefits," 30 U.S.C. s 923(b) (incorporating 42 U.S.C. s 405(a)). Nor do the revised rules set inflexible limits, as NMA claims. On the contrary, the rules give ALJs discretion to hear additional evidence for "good cause," 20 C.F.R. s 725.456(b)(1).

NMA claims that the evidence-limiting rules are also arbitrary and capricious because they are unsupported by medical evidence. NMA bases this claim on a commenter's argument that "it is unreasonable to artificially limit" the amount of evidence heard in benefits determinations. Cmts. of Drs. Fino and Bahl at 4, reprinted in J.A. 2432. Other record evidence, however, indicates that the new evidentiary limits are not at all "artificial[]," but - as the Secretary explained will enable ALJs to focus their attention "on the quality of the medical evidence in the record before [them]." 64 Fed. Reg. at 54,994. The record also makes clear the need for evidence limitations; in their absence, lawyers often waste ALJs' time and resources with excessive evidence - in one case, a mine operator's lawyer submitted eighty-nine separate X-ray rereadings from fourteen different experts. Cmts. of Robert Cohen at 71 (6/19/1997), reprinted in J.A. 1381. At oral argument, moreover, NMA conceded that ALJs have always had discretion to exclude evidence in precisely the manner outlined by the new evidence-limiting rules; it would be strange indeed to conclude that the Secretary acted arbitrarily and capriciously by codifying evidentiary limits that ALJs have always had the discretion to impose.

Dependency Rules

The Black Lung Benefits Act incorporates the Social Security Act's definition of "dependent." See 30 U.S.C. s 902(a) (incorporating the Social Security Act's definition of "dependents"). These regulations (ss 725.204, 725.213(c), 725.214, 725.219(d)) broaden the definition of "dependent" to track

more closely recent revisions of the incorporated Social Security Act provisions. Like the District Court, though, we decline to consider this claim, because NMA failed to raise it during the notice-and-comment period. See, e.g., Nat'l Wildlife Fed'n v. EPA, 286 F.3d 554, 562 (D.C. Cir. 2002) ("It is well established that issues not raised in comments before the agency are waived and this Court will not consider them."). NMA points out that it argued before the agency that "Congress did not intend to treat the black lung program as a social safety net," Br. for Appellants at 69, but this general claim falls well short of providing the agency with the required "adequate notice" of NMA's specific claim. Nat'l Recycling Coalition, Inc. v. Reilly, 884 F.2d 1431, 1437 (D.C. Cir. 1989). Contrary to NMA's argument, moreover, this notice requirement is not undermined by Darby v. Cisneros, 509 U.S. 137 (1993), and Sims v. Apfel, 530 U.S. 103 (2000). As we recently noted, Darby "addresses exhaustion of remedies, not waiver of claims, and is thus wholly inapposite" to the latter issue. Nat'l Wildlife Fed'n, 286 F.3d at 562. Sims is equally inapplicable, for it addresses issue exhaustion, not issue waiver.

Attorney's Fee Rule

Section 725.366(b) provides that in calculating attorney's fees that are shifted from claimant to mine operator, the ALJ "shall take into account" a number of factors, including "the quality of the representation, the qualifications of the representative, [and] the complexity of the legal issues involved." In Burlington v. Dague, the Supreme Court held that shifted attorney's fees must be calculated according to the "lodestar method," which requires that such fees be determined by multiplying reasonable time spent by the attorney's hourly fee. See 505 U.S. 557, 562 (1992). Although the revised regulation requires consideration of no factors not already included in the lodestar analysis, NMA argues that the rule will require ALJs to consider some factors more than once, resulting in prohibited "double counting." Br. for Appellants at 67; see Pennsylvania v. Delaware Valley City Council, 483 U.S. 711, 726 (1987). Not only does nothing in the revised regulation require such double counting, but the Secretary

interprets the regulation to mean that "the factors identified in s 725.366(b) do not supplant the 'lodestar' method of calculating reasonable fees, or enhance the lodestar fee once it is calculated." Br. for Appellees at 54.

Cost and Expense Rules

Section 725.101(a)(6) (the cost rule) expands the definition of BLBA "benefits" to include "any expenses related to the medical authorization." As a result, employers now bear the costs of successful claimants' medical examinations. Section 725.459 (the expense rule) empowers ALJs in their discretion to shift costs incurred by claimants' production of witnesses to an employer, regardless of which party prevails.

NMA rests its challenge to these regulations on the twin premises that parties presumptively bear the costs of their own litigation expenditures and that such costs may only be shifted to the losing party pursuant to "specific statutory authorization." See W. Va. Univ. Hosp. v. Casey, 499 U.S. 83, 97-100 (1991). The cost rule, however, finds just such "specific statutory authorization" in the Black Lung Benefits Act's express authorization to "[t]he Secretary ... to charge the cost of examination ... to the employer." 33 U.S.C. s 907(e).

In support of the expense rule, the Secretary first cites 33 U.S.C. s 928(d), which permits her to shift attorney's fees. But that section of the Act authorizes fee-shifting only when the claimant prevails, while the expense rule authorizes such shifting for both successful and unsuccessful claimants. Nor does 30 U.S.C. s 907(e) provide an adequate source of authority; that clause only permits the Secretary to assign costs of a single pulmonary examination - not any cost associated with claimants' witnesses - to the employer. The expense rule thus lacks the "specific statutory authorization" for feeshifting required by Casey and is the one regulation that we find invalid on its face.

III. Conclusion

For the foregoing reasons, we affirm in part, reverse in part, and remand to the District Court for further proceedings consistent with this opinion.